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HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/106,172	06/26/98	TULLY	R 0/97293US

HM22/0824

WILLIAM M BLACKSTONE  
AKZO NOBEL  
1300 PICCARD DRIVE #206  
ROCKVILLE MD 20850-4373

EXAMINER

KRASS, F

ART UNIT	PAPER NUMBER
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1614

10

DATE MAILED: 08/24/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/106,172

Applicant(s)  
Tully et al.

Examiner  
Frederick Krass

Group Art Unit  
1614



☒ Responsive to communication(s) filed on Jul 15, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-11 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1 is/are rejected.

☒ Claim(s) 2-11 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☒ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **Previous Rejections**

All previous rejections should be considered withdrawn unless specifically repeated hereinunder.

### **Obviousness Rejection**

Claim 1 was rejected as being unpatentable over WO84/01506.

This rejection is maintained.

Applicants argue that the prior art pertains to parenteral solutions, not oral administrative forms. This is not so; oral dosage forms are taught at page 3, line 5. The fact that NMP may be unacceptable for oral administration to human patients in the United States does not preclude use in animals (for pharmacologic studies, etc) nor use in third world countries. Moreover, claim 1 requires that the solution "can be" administered orally. NMP solutions "can be" administered even to humans in developed countries, and the fact that they may not be desirable or even suitable for that purpose does not mean the use is not obvious; it should be remembered that the legal standards for obviousness in patent law are not the same as, nor even pertinent to, standards of safety and efficacy as established by the Food and Drug Administration.

### **Allowable Subject Matter**

Claims 2-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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**Action is Final**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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### Correspondence

Any inquiry concerning this communication or earlier communications regarding the substantive aspects of the communication (the action *per se*, questions regarding patentability, etc) from the examiner should be directed to Frederick Krass whose telephone number is (703) 308-4335. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

The examiner generally returns his phone calls in a very prompt manner. If attempts to reach the examiner by telephone are unsuccessful (allowing for a few days in case the examiner is on sick leave), the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Frederick Krass  
Primary Examiner  
Art Unit 1614

